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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,097	10/27/2003	James D. Hughett	0341-0003.15	3110

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EXAMINER	
VENIAMINOV, NIKITA R	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

CS

Office Action Summary	Application No.	Applicant(s)	
	10/694,097	HUGHETT ET AL.	
	Examiner	Art Unit	
	Nikita R Veniaminov	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 12-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 12-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 27 October 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. **Claims 12 and 15-17** are rejected under 35 U.S.C. 102(b) as being anticipated by Saab (US 5,624,392). Saab ('392) teaches

Claim 12 (independent)

a catheter (100) having a proximal end and a distal end for use in a intraluminal treatment system wherein a treating element is advanced from the proximal end of the catheter to the distal end by use of pressurized fluid (Examiner states that the underlined phrase is directed to the intended use, thus does not reflect any structural limitations set forth in the claim), the catheter (100) comprising: first (108), second (110), third (114) and fourth (112) lumens extending substantially from the proximal end to the distal end of the catheter, the first lumen (108) being sized to slidingly receive the treating element but to prevent the treating element from exiting the first lumen at the distal end of the catheter (column 16, lines 43-46), the first lumen (108) being in fluid communication with the second (110) and third (114) lumens at the distal end thereof, and the fourth lumen (112) being open at the distal end (column 16, lines 34-67) and sized to receive a guidewire (Examiner states that the phrase "sized to receive a guidewire" does not reflect

any structural limitations and is directed to the intended use of the claimed apparatus);

Claims 15-17

the catheter of Claim 12 wherein the proximal and distal ends of the catheter are of different stiffness and flexibility, and the distal end has a cross-sectional area smaller than the proximal end of the catheter and a non-circular cross-sectional shape so as to permit perfusion; wherein the proximal end is fused to the distal end; or wherein the proximal end and distal end are formed through a single variable extrusion (column 16, lines 59-67 and column 17, lines 1-3).

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. **Claims 13 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab (US 5,624,392) as applied to claim 12 above, in view of Machold et al. (US 4,976,720).

Saab ('392) teaches a catheter, as described in paragraph 2 above, but he does not teach a fourth lumen, which includes a protective liner, which is polyimide.

Machold et al. ('720) teach a catheter having an inner tubular protective member with an inner lumen to receive a guidewire formed of a thin-walled tubing such as polyimide tubing (abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to implement the polyimide tubing of Machold et al. ('720) as a protective liner of the guidewire lumen of Saab ('392) in order to provide extra durability and lubricate the walls of said lumen for easier manipulation of the catheter of Saab ('392) over the guidewire, as taught by Machold et al. ('720).

5. **Claims 12 and 15-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman et al. (US 5,683,345) in view of Saab (US 5,624,392). Waksman et al. ('345) teach

Claim 12 (independent)

a catheter (88) having a proximal end and a distal end for use in a intraluminal treatment system wherein a treating element is advanced from the proximal end of the catheter to the distal end by use of pressurized fluid (abstract; Figure 2C and column 9, lines 8-22), the catheter (88) comprising: first (118), second (122) and third (124) lumens extending substantially from the proximal end to the distal end of the catheter, the first lumen (118) being sized to slidingly receive the treating element but to prevent the treating element from exiting the first lumen at the distal end of the catheter (column 9, lines 24-33), the first lumen (118) being in fluid communication with the second (122) lumens at the distal end thereof, and the third lumen (124) being open at the distal end and sized to receive a guidewire (column 6, lines 8-22).

However, Waksman et al. ('345) do not teach a catheter, having four lumens, wherein the proximal and distal ends of the catheter are of different stiffness and flexibility, and the distal end has a cross-sectional area smaller than the proximal end of the catheter and a non-circular cross-sectional shape so as to permit perfusion; wherein the proximal end is fused to the distal end; or wherein the proximal end and distal end are formed through a single variable extrusion. Saab ('392) teaches a catheter having four lumens and wherein the proximal and distal ends of the catheter are of different stiffness and flexibility, and the distal end has a cross-sectional area smaller than the proximal end of the catheter and a non-circular cross-sectional shape so as to permit perfusion; wherein the proximal end is fused to the distal end; or wherein the proximal end and distal end are formed through a single variable extrusion (see paragraph 2 above).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the catheter of Waksman et al. ('345) by the catheter of Saab ('392) to provide an extra lumen to provide utilize more sufficient fluid exchange inside the catheter, as taught by Saab ('392).

Also, in the absence of showing any criticality it would have been obvious to one of ordinary skill in the art at the time of invention to implement a fourth lumen in the catheter of Waksman et al. ('345), since duplicating the lumens of the catheter of Waksman et al. ('345) is a design consideration within the skill of the art [In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)].

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rydell et al. ('182) ; Slepian et al. ('977) ; Nix et al. ('921); Peacock, III ('995) and Chiu et al. ('734).

Response to Arguments

7. Applicant's arguments with respect to claim 12-17 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (571) 272-4735. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nikita R Veniaminov
Examiner
Art Unit 3736

November 15, 2004.

SAMUEL G. GILBERT
PRIMARY EXAMINER